1

## METHOD OF TREATING PEYRONIE'S DISEASE

## **BACKGROUND**

Peyronie's disease is manifested by an abnormal bend that occurs in the erect penis of the sufferer and can be associated with painful erection and/or painful intercourse.

Peyronie's disease is related to the development of scar tissue, or plaques, that form on tissues (e.g., tunica albuginea) 10 inside the penis. One non-surgical approach for the treatment of Peyronie's disease includes injecting drugs into the plaques that lessen the compression applied by the plaques to the erect penis. The research and efficacy of this approach is limited

Surgical treatments for Peyronie's disease include excising portions of the tunica albuginea from the penis opposite the plaque and closing the fenestrations with sutures. Access to the tunica albuginea is achieved by first degloving the penile skin away from the penis to expose the Buck's fascia and 20 tunica albuginea along the length of the penis. Degloving the penile skin is painful and the recovery time for the patient can be several weeks. Although the long term results of this surgical approach are good, both short term (within 8 weeks) and long term failures can present with residual penile deformity. 25

Another surgical treatment includes corporal plication in which plication sutures are placed on the contralateral side of the plaque without excising the tunica albuginea or removing the plaque. Corporal plication is most commonly employed subsequent to a previous Peyronie's treatment surgery to <sup>30</sup> correct small angles of residual penile deformity.

Patients and clinicians desire more effective treatments for Peyronie's disease.

## **SUMMARY**

One aspect provides an implant that includes one or more sheet components attached to at least one reinforcing component. The at least one reinforcing component provides column strength to the implant and the one or more sheet components provides support for penile tissue. The implant is adapted to be positioned on a Peyronie's plaques affected area of a penis. The implant is configured to elongate during an erection of the penis and to contract when the penis returns to its flaccid state.

One aspect provides an implant for treatment of Peyronie's disease. The implant includes a skeletal framework having one or more sheet components attached to at least one reinforcing component to support penile tissue and to provide a flexible, yet strong and durable implant. The sheet components are at least partly made from a biocompatible material. The implant is placed subcutaneously on an affected area of the penis. The skeletal framework of the implant allows for elongation of the implant during erection of the penis and for contraction of the implant when the penis is returning to its flaccid state. To secure the implant to the penis, the skeletal framework includes at least one attachment mechanism.

One aspect provides an implant that includes a skeletal framework having one or more sheet components attached to a plurality of reinforcing components that provide column strength along a longitudinal direction of the implant and the sheet components provide support for penile tissue. The skeletal framework of the implant allows for elongation of the implant during erection of the penis and for contraction of the implant when the penis is returning to its flaccid state.

One aspect provides an implant that includes a skeletal framework having one or more sheet components attached to 2

at least one reinforcing component that provide support for penile tissue and column strength to the implant, respectively. The implant is configured to be placed underneath the upper skin layer of the penis (e.g. on the tunica albuginea, T.A.) on an affected area of the penis and forms an arch describing 180 degrees or less.

One aspect provides an implant that includes a skeletal framework having one or more sheet components attached to a plurality of reinforcing components and at least one attachment mechanism including a suture line attached to the skeletal framework at one end and a hook-shaped needle for tissue penetration attached at a second end of the suture line and at least one anchor provided on the suture line for securing the implant to the penis.

One aspect provides a method of treating Peyronie's disease. The method includes implanting an implant including one or more sheet components attached to a reinforcing component. The method includes performing an incision to gain access to the penile tissue affected by the Peyronie's plaques and excising the scar tissue. The method includes providing the implant on the affected area. The method includes positioning the implant so as to provide for optimal tissue ingrowth and for optimizing column strength in the implant. The method includes securing the implant to the penis. The method includes closing the incision.

Embodiments provide an implant that eliminates or reduces the physical effects of the Peyronie's disease. Embodiments of the implant described in this application have improved sustainability and durability and thus reduces or eliminates the potential for surgical revision and/or substitution of the implant. A further object is to provide a Peyronie's treatment implant that is easily manageable and has improved flexibility in order to improve patient perception and comfort. A further object is to provide an implant that supports and reinforces the affected penile tissue area where the plaques have been removed. A still further object is to provide an implant that is easily implantable and obviates the use of other tools to attach the implant to the penile tissue. A further objective is to provide another alternative to a medicament based treatment option for Peyronie's disease.

## BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings are included to provide a further understanding of embodiments and are incorporated in and constitute a part of this specification. The drawings illustrate embodiments and together with the description serve to explain principles of embodiments. Other embodiments and many of the intended advantages of embodiments will be readily appreciated as they become better understood by reference to the following detailed description. The elements of the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding similar parts.

FIG. 1A is a top view of one embodiment of an implant.

FIG. 1B is a top view of one embodiment of an implant.

framework having one or more sheet components attached to a plurality of reinforcing components that provide column for the implant and the strength along a longitudinal direction of the implant and the formula of FIG. 1B is a perspective view of an erect penis afflicted by Peyronie's disease indicating where the implant of FIG. 1B is to be applied on the penis.

FIG. 1D is a side schematic view of the penis illustrated in FIG. 1C in a flaccid state and including an implant attached to the tunica albuginea of the penis.

FIG. 1E is a side schematic view of the penis illustrated in FIG. 1D in an erect state having reduced curvature as compared to the untreated penis illustrated in FIG. 1C.